PCT/PTO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Yoshimura and Kamohara

Application No. 10/507,385

Filed: September 9, 2004

Confirmation No. 8908

For: USE OF DISCOIDIN DOMAIN RECEPTOR 1 (DDR1) AND AGENTS THAT AFFECT THE DDR1/COLLAGEN PATHWAY

Examiner: Maria Gomez Leavitt

Art Unit: 1633

Attorney Reference No. 4239-64104-02

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: MAIL STOP PETITION, OFFICE OF PETITIONS, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Attorney or Agent for Applicant(s) Anne Carlson

Date Mailed May 12, 2008

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TRANSMITTAL LETTER

Enclosed for filing in the application referenced above are the following:

☒ Petition to Have Finding of Lack of Unity/Restriction Requirement Reconsidered under 37 CFR § 1.144

☒ A check in the amount of $130.00 to cover the above-listed fees

☒ The Director is hereby authorized to charge any additional fees that may be required, or credit over-payment, to Deposit Account No. 02-4550. A copy of this sheet is enclosed.

☒ Please return the enclosed postcard to confirm that the items listed above have been received.

05/19/2008 GFREYI 00000098 10507385
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Respectfully submitted,

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PETITION TO HAVE FINDING OF LACK OF UNITY/RESTRICTION REQUIREMENT RECONSIDERED UNDER 37 CFR § 1.144

Pursuant to 37 C.F.R. 1.144, Applicants petition the requirement for restriction mailed January 3, 2007. Applicants have preserved the right to petition by timely traversing the requirement for restriction in Applicant's response mailed February 5, 2007. Applicants submit herewith a petition fee of $130.00. In the event that additional fees are required in conjunction with the filing of this Petition, the Office is hereby authorized to obtain such fees from Deposit Account 02-4550.

A. The invention

As described in the specification, the present invention is generally directed to methods of using activated Discoidin Domain Receptor 1 (DDR1) to induce the maturation of immature leukocytes (*i.e.*, macrophages, monocytes, neutrophils, or lymphocytes) or immature dendritic cells. In turn, the activation of DDR1 enhances the activities of these cells. Such activities include antigen presentation to T cells, cytokine and/or chemokine production, and leukocyte

migration. Thus, activated DDR1 (and agents that activate DDR1) can be used to enhance an immune response in a subject. Alternatively, agents that inhibit DDR1 activation can be used to reduce or inhibit an immune response in a subject.

B. Restriction Requirement

In an Office action dated January 3, 2007, the claims were restricted into seven Groups (Groups I-VII) because the special technical feature linking the claims does not define a contribution over the prior art, as required under PCT Rule 13.2. Applicants respectfully disagree and petition to withdraw the restriction requirement.

C. The Restriction Requirement is Improper Because the Special Technical Feature of the Claims Defines a Contribution over the Prior Art

The Office action acknowledges that a special technical feature links the invention of Groups I-VII. Specifically, the technical feature linking Groups I-VII "are methods for activation of DDR1 by a DDR1-activating agent which induces the maturation of a dendritic cell precursor, for example a monocyte, into a macrophage or a dendritic cell. Moreover, the methods teach that contacting a dendritic cell precursor with an antigen, in addition to a DDR1-activating agent, can induce the maturation of the dendritic cell precursor into an antigen-presenting dendritic cell. Thus, in the claimed methods, the activation of DDR1 can enhance antigen presentation to T cells and enhance T cell responses in a subject" (Office action at page 3). However, the Office action further alleges that the "special technical feature linking the invention of Groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over [the] prior art" (Office action at page 4). In support of this statement, the Office cited Bhatt *et al.* (*Genes Dev.*, 14(17):2216-2228, 2000 – **Exhibit A**), which "described a functional role for activators of the DDR1 in the developing cerebellum facilitating granule neuron axon outgrowth toward establishing proper connections with Purkinje neurons" (Office action at page 4). Applicants respectfully submit that the restriction of the claims based on Bhatt *et al.* is improper and that all of the Groups do in fact relate to a single special technical feature, which feature makes a contribution over the prior art. As such, all of the claims should be examined together.

In the present Application, the pending claims satisfy the requirements of Rule 13.1 and Rule 13.2. For convenience, these rules are set forth below:

Rule 13.1

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

Rule 13. 2

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The Office action alleges that as Bhatt *et al.* discloses a functional role for activators of the Discoidin Domain Receptor 1 (DDR1) in developing cerebellum facilitating granule neuron axon outgrowth, the claims are not defined by a special technical feature that makes a contribution over the prior art. However, Applicants submit that the special technical relationship linking the Groups of claims, namely that the activation of DDR1 induces the maturation of an immature dendritic cell into a mature dendritic cell, does make a contribution over the prior art.

Bhatt *et al.* discloses a functional role for activation of DDR1 in the *granule cells* of the developing cerebellum. Bhatt *et al.* does not disclose a role for activation of DDR1 in immature *dendritic cells*, as required by the claims, nor does Bhatt *et al.* disclose dendritic cells. As defined by the specification, a dendritic cell is "derived from hematopoietic stem cells in the bone marrow" (page 12, line 12) and is "the principle antigen presenting cell involved in primary immune responses" (page 11, lines 30-31). Although neurons have morphological features

known as dendrites, neurons are not "dendritic cells," as defined by the specification. Thus, Bhatt *et al.* does not anticipate the claims.

Bhatt *et al.* also discloses that DDR1 is specifically involved in the elongation of neurites (axons or dendrites), but that DDR1 does not play a role in the commitment of the cells to terminal differentiation (see, for example, page 2223, paragraph bridging left and right columns). However, Bhatt *et al.* describes another gene (*Unc51.1*) which is involved in both neurite outgrowth and terminal differentiation (see page 2223, paragraph bridging left and right columns). Thus, the mere fact that DDR1 is involved in the development of a very specific morphological feature (neurites), does not predict that it plays a role in the general process of differentiation (or maturation), as required by the claims. Moreover, neurites are not found on dendritic cells. As such, the activity of DDR1 in granule cells is irrelevant with regard to dendritic cells. Accordingly, one of skill in the art would not have predicted, based on the teachings of Bhatt *et al.*, that DDR1 could be used to induce the maturation of an immature dendritic cell. Thus, the pending claims are not obvious in light of Bhatt *et al.*

In light of the above arguments, Applicants respectfully submit that the special technical feature of the claims is both novel and non-obvious and does, in fact, define a contribution over the prior art. Applicants believe that the present application complies with Rules 13.1 and Rules 13.2 and that the claims should be examined together.

D. Conclusion

In light of the above discussion, Applicants respectfully petition the Commissioner to withdraw the Examiner's improper restriction requirement and allow all the pending claims to be examined.

Respectfully submitted,

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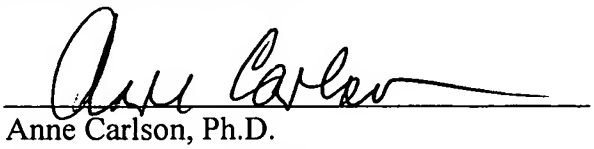
By 

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